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10/596,970	06/30/2006	Leona Gabrizova	MHOL-P-004	3352
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Oppedahl Patent Law Firm LLC P.O. BOX 4850 FRISCO, CO 80443-4850			MANO哈尔, MANU M	
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			1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/596,970	Applicant(s) GABRIZOVA, LEONA
	Examiner MANU M. MANOHAR	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 01 November 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6 & 8 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 6 and 8 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/DP/0656)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on November 01, 2008. Claims 6 and 8 are pending. Claims 1-5, 7 and 9-17 are cancelled. Claim 6 is presently amended. Thus Claims 6 and 8 are examined herein.

Rejections

Applicant's amendment of claim 6 is acknowledged and hence the 35 U.S.C. 112, second paragraph, rejection of claim 6 of the previous office action is withdrawn. The 35 U.S.C. 112, second paragraph rejections of claims 14-17 are rendered moot now since the applicant cancelled these claims.

Applicant's arguments against the 35 USC 103(a) rejection of claims 6-13 over Wheatcroft et al, US Patent 6,444,448, in view of Hunter et al, US Patent Application US 2002/0192280 have been fully considered but found not persuasive. The rejections of the 103(a) rejection of last Office Action are maintained for reasons of record but in view of their amendments to the claim 6 the following modified 35 USC 103(a) rejection is herein made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheatcroft et al , US Patent 6,444,448.

The instant invention is the method of preparation of a fungal glucan hydrogel having antibacterial activity. The instant claim 6 is drawn to a method of preparation of a fungal glucan from *Pleurotus ostreatus* by various steps and claim 8 is drawn to the property of the resulting gel as containing beta-(1,3)- D bond branched at every fourth anhydroglucose unit.

Wheatcroft et al teaches the production of Beta-glucan with anti-infective property (column 1-line 41-43, line 45-47) and immunostimulatory activity (Abstract-line 1-3) from microorganisms including *Pleurotus ostreatus* (column 5-line 21, column 18 claim 17). Wheatcroft et al teaches the use of alkali, defibration (Column 7 line 39-42) and the steps for the elimination of water soluble components (Column 7 line 46-49). Wheatcroft et al also teaches hydration and the preparation of hydrogel in the viscous

form using homogenizer, [wet grinding (Column 10- line 65 to column 11- line 9)].

Wheatcroft et al also teaches the preparation of hydrogel by the boiling for 10 minutes (column 12, table VIII) in the final step even though it does not state that the heating is for sterilization. In addition Wheatcroft et al teaches glucan formed contain glucose with beta-1,3- bond as claimed in the instant claim 8 (column 1-line 17-28, column 20 claim 25) and percentage of glucans with 1-3 linked linkages can vary according the method of preparation (column 9 Table III). In addition Wheatcroft et al states that the preparation of purified beta (1-3) glucan with alkali-acid extraction procedure is well known in the art and also refers to a previous art for the same preparation (column 7 line 34-37).

Moreover one of the ordinary skill in the art would expect same products, 1,3-linked and 1,6 linked hydrogel, prepared by the same steps as taught by Wheatcroft et al from *Pleurotus osteratus* unless the evidences are present to contrary that only 1,3-linked hydrogel are obtained by the procedure.

Wheatcroft et al fail to disclose the exact specific parameters for the preparation of hydrogel like- rotational speed of 3000-9000 rpm for 10 -20 minutes for wet grinding, water content and the heating for 20-30 minutes at 90 -110 degrees C in the final step and also does not disclose the concentration of beta 1-3 bond as 0.5 to 3% although it teaches the general various parameters. Wheatcroft also does not specifically teach that beta 1,3 D bond is branched at every fourth glucose unit.

However, when the general conditions of a claim are disclosed by Wheatcroft et al, it is obvious to one of ordinary skill in the art to modify these parameters to various ranges by routine experimentation to obtain a desired product.

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382; It has been held that it is within the skills in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 1980) MPEP 2114.04.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to develop a immunostimulant hydrogel with beta 1,3 bond from *Pleurotus ostreatus* as taught by Wheatcroft et al with a routine optimization like alkaline deproteination, elimination of water-soluble components, wet grinding and finally preparing the gel with heat and adjusting the concentration of glucan with beta 1,3 D linkage.

One of the ordinary skill in the art would be motivated to prepare the fungal glucan hydrogel with immunostimulant property because Wheatcroft et al teaches the

preparation of glucan hydrogel from microorganisms including *Pleurotus ostreatus*.

Optimization of the parameters for the preparation of hydrogel like -alkaline deproteination subsequent elimination of water-soluble components, wet grinding of the insoluble glucan with various time and rotational speed, preparing the gel with heat at different temperature and time and obtaining the glucan with beta 1,3 D linkage with desired percentage - is obvious to one of ordinary skill in the art and of routine practice. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in preparing fungal glucan hydrogel as taught by Wheatcroft et al.

Response to Arguments

The amendment for the claim 6 and the addition of new limitation is noted.

The applicants argue that Wheatcroft et al teaches homogenizing not wet grinding and the intermediate product are different because the invention is the preparation of fungal beta-glucan produced from *Pleurotus osteratus* not from yeast, whereas Wheatcroft et al teaches the beta-glucan mannan by the autolysis of yeast. In addition the applicant state that the intermediate products are different and possess different physical and chemical properties.

The examiner is taking the position that homogenizing is one form of wet grinding. In fact applicant state in the specification that wet grinding using high speed mixer (Page 3 Example 1) for hydrating glucan prepared from *Pleurotus osteratus* and

homogenizer (Page 3 line 2 of example 2) for preparing cream of glucan hydrogel.

Wheatcraft teaches the use of homogenizer for preparation of viscous product of glucan-mannan in the form whipped cream (Column 10- line 65 to column 11- line 9).

Moreover Wheatcraft teaches that the preparation of fungal beta-glucan from *Pleurotus osteratus* (column 5-line 21, column 18 claim 17) with same steps like alkaline treatment (column 7 line 39-42), elimination of water soluble components (column 7 line 46-49), wet grinding (homogenizer (column 11 line 1-5) and result in the products including the product the applicant claimed, polysaccharide with beta (1,3) linkage (column 9 Table III) and one of ordinary skill in the art expect that the intermediate and final products of the invention and the prior art would be the same.

The applicant argues that Wheatcroft's process is different with respect to the content of water used for swelling, the rotational speed used in the wet grinding and the temperature used for sterilization.

This is not persuasive because Wheatcroft et al teaches that the preparation with water using homogenizer (wet grinding) which can result in the form viscous product (Column 10- line 65 to column 11- line 9) and the glucan can also be prepared in the form of gel or cream (Column 12-line 66-67). Wheatcroft et al also teaches the percentage of water can be 10% and 20% of dry weight (column 10-line 63-66). The Beta glucan described by the Wheatcroft comprises a beta- 1, 3 bond (Column 1-line 32, column 17-claim 1, column 20-claims 24 and 25). It also teaches the property of the glucan can be altered with heat, for example by boiling the glucan for 10 minutes (column 12 Table VIII).

Applicant further argue that the product in the claimed invention is formed only by fungal polysaccharide with the beta-(1,3)-bond branched at every fourth anhydroglucose unit and does not comprise 1, 6-linked glucose monomers and with the Wheatcroft's teaching it is impossible to achieve the claimed structure.

Examiner is taking the position that Wheatcroft in general teaches the basic steps as set forth above for the preparation of immunostimulant from microorganisms including from *Pleurotus osteratus*. The product obtained by Wheatcroft et al includes the product of the claimed invention the fungal polysaccharide with the beta-(1,3)-bond. (Column 9 Table III, column 20 claim 25). Moreover Wheatcroft et al states that the preparation of purified beta (1-3) glucan with alkali-acid extraction procedure is well known and refers to a prior art (column 7 line 34-37). One of the ordinary skill in the art would expect same intermediate and final products as taught by Wheatcroft et al from *Pleurotus osteratus* by using the same steps unless the evidences are present to contrary, for example, demonstrating that the instant intermediate and final products are different and the final product contain only glucan with beta(1,3)-D-bond as claimed.

In addition Wheatcraft teaches that the preparation of fungal beta-glucan from *Pleurotus osteratus* (column 5-line 21, column 18 claim 17) with the same functional steps like alkaline treatment (column 7 line 39-42), elimination of water soluble components (column 7 line 46-49), and wet grinding (homogenizer (column 11 line 1-5) in the process of making the hydrogel from the same source *Pleurotus osteratus* hence any resulting properties such as a beta-(1,3)-D bond being branched at every fourth anhydroglucose unit, is inseparable from the composition.

When the product recited in the reference is substantially identical to that of the claims and the product are produced by substantially identical process, claimed properties are presumed to be the same. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusions

Claims 6 and 8 are stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 1617

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